

MAY 04 2006

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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) <b>TP1039</b>
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on <u>May 4, 2006</u>		Application Number: <b>10/820,382</b>
Signature <u><i>Kristin Miele</i></u>		Filed: <b>4/8/2004</b>
Type or Printed Name <u><i>Kristin Miele</i></u>		First Name Inventor: <b>Matthew Peterson</b>
		Art Unit: <b>1625</b> Examiner: <b>Celia C. Chang</b>

Applicant requests review of the final rejection in the above-entitled application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated of the attached sheet(s).  
Note: No more than five (5) pages may be provided.

- I am the
- ☐ applicant/inventor.
  - ☐ assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).
  - ☒ attorney or agent of record. Registration Number 53,852
  - ☐ attorney or agent under 37 CFR 1.34(a).  
Registration number if acting under 37 CFR 1.34(a) \_\_\_\_\_

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Paul Burgess  
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NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

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This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Matthew Peterson et al.

Serial No.: 10/820,382

Group No.: 1625

Filed: 04/08/2004

Examiner: Celia C. Chang

For: GABAPENTIN COMPOSITIONS

Attorney Docket Number: TPIP039

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Dear Sir:

This invention relates to novel and unknown crystalline salts of gabapentin. In the first Office Action, the Examiner rejected the pending claims as obvious in view of one reference disclosing known gabapentin hydrochloride and a couple of other references disclosing multiple acid/base pair possibilities useful in pharmaceuticals, but not specific to gabapentin. Applicants' subsequent response included arguments refuting both the motivation to combine and the reasonable expectation of success of novel gabapentin salt formation given the cited references. Examiner's second and final Office Action maintained the same rejections without further analysis or apparent consideration of Applicants' arguments. Applicants filed an after-final response with a recently published article which demonstrates the current unpredictability of salt formation. Applicants received an Advisory Action in which the Examiner apparently gave no weight to the recently published article.

Applicants are requesting a pre-appeal brief conference because the Examiner has not considered the persuasive reference which Applicants have submitted and believe overcomes the

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Kristin Miele

obviousness rejection. The recently published article describes the unpredictability of salt formation for any one particular drug and one particular acid/base pair (April 8, 2006 Response, last paragraph of page 9). The Examiner did not discuss this dispositive reference in her subsequent Advisory Action and incorrectly stated that "No factual evidence supports unexpectancy was made in the record." In fact, the reference specifically states that "...there exists no a priori prediction procedure to determine the feasibility of salt formation in a given acid-base pair." This statement alone should support the patentability of Applicants' novel gabapentin salts.

Applicants' other non-obviousness arguments are:


- 1) The references cited by the Examiner simply state gabapentin can exist as a hydrochloride salt and that other known drugs can form salts with other acid/base pairs. These references do not make obvious particular salts of gabapentin. This argument is also refuted by Applicants' cited reference describing the unpredictability of salt formation.
- 2) The references cited by the Examiner fail to teach or suggest how to create the particular salts identified by Applicants. Example 1 of Applicants' application discloses a very specific method for the formation of the novel gabapentin DL-tartaric acid salt with a particular novel PXRD pattern. This pattern is compared to the previously known forms of gabapentin and is shown to be different. The Examiner's references do not suggest the method described in Example 1 or in the other examples.
- 3) Examiner's contention that "the physical property of a compound is the innate nature of that product" (See April 28, 2005 Office Action, last paragraph of page 3) is not a proper obviousness analysis. None of the salts claimed are the innate nature of any of the references the Examiner has cited. The novel salts identified in Applicants' application are not the innate result of the known gabapentin hydrochloride disclosed in Augart et al. or in any other reference relied upon by Examiner.
- 4) It is not obvious that the resultant novel salts would be crystalline. The physical state of the salt (i.e., amorphous or crystalline), the particular physical structure, and the properties associated with a particular structure cannot be predicted. Just as the recently published article confirms the unpredictability of salt formation, it is equally unpredictable that the resultant novel

salt would be crystalline. As such, each of the claimed novel crystalline salts represents an unexpected result.

Applicants believe the Examiner has not properly considered its arguments, and more importantly, has not considered the recently published persuasive article. Accordingly, Applicants respectfully request withdrawal of the obviousness rejections.

Respectfully submitted,

May 4, 2006, 2006  
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